DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Astelin®
Docket No. 97E-0014

MAR 27 1997

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APR - 3 1997

PATENT EXTENSION
A/C PATENTS

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 5,164,194, filed by Astra Medica AG, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Astelin®, the human drug product claimed by the patent.

The total length of the regulatory review period for Astelin is 2,797 days. Of this time, 749 days occurred during the testing phase and 2,048 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: March 8, 1989.

   The applicant claims February 6, 1989, as the date the Investigational New Drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 8, 1989, which was thirty days after FDA receipt of the IND on February 6, 1989.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: March 26, 1991.

   FDA has verified the applicant's claim that the New Drug Application (NDA) for Astelin (NDA 20-114) was initially submitted on March 26, 1991.

3. The date the application was approved: November 1, 1996.

   FDA has verified the applicant's claim that NDA 20-114 was approved on November 1, 1996.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

for Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Kevin B. Clarke, Esq.
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New York, NY 10105